DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2015

Medtronic Advanced Energy
Lydia Sakakeeny, Ph.D.
Principal Regulatory Affairs Specialist
180 International Drive
Portsmouth, New Hampshire 03801

Re: K150297
Trade/Device Name: PEAK PlasmaBlade UPPP and Suction Coagulator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 24, 2015
Received: April 28, 2015

Dear Dr. Sakakeeny:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150297

Device Name:
PEAK PlasmaBlade UPPP

Indications for Use:
The PEAK PlasmaBlade UPPP is indicated for cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including, uvulopalatopharyngoplasty (UPPP) and tonsillectomy (Pharyngeal, Tubal, Palatine).

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K150297

Device Name:
PEAK PlasmaBlade Suction Coagulator

Indications for Use:
The PEAK PlasmaBlade Suction Coagulator device is intended for use in surgical procedures such as general and otolaryngology (ENT) including, uvulopalatopharyngoplasty (UPPP), tonsillectomy, and adenoidectomy, where coagulation of tissue and suction of fluids are desired. It is not intended to be used as a dissection instrument.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Summary

Submitter:	Medtronic Advanced Energy 180 International Drive Portsmouth, NH 03801
Contact Person:	Lydia Sakakeeny, PhD Principal Regulatory Affairs Specialist Phone: (603) 294-5482 Fax: (603) 742-1488 E-mail: lydia.sakakeeny@medtronic.com
Date Summary Prepared:	March 13, 2015
Device Trade Name:	PEAK PlasmaBlade UPPP and Suction Coagulator PEAK PlasmaBlade Suction Coagulator
Common Name:	Electrosurgical Instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Product Code:	GEI
Predicate Device:	K083415 PEAK PlasmaBlade TnA (Tonsil Tip PS300-001) K014290 (Original) Arthrocare ENT Plasma Wands K103775 PEAK PlasmaBlade Suction Coagulator
Device Description:	The PEAK PlasmaBlade® UPPP and Suction Coagulator is a single-use, disposable, electrosurgical instrument consisting of two PlasmaBlade tips (UPPP tip and Suction Coagulator tip) designed to be attached to the Plasmablade ENT handpiece (cleared as the PEAK Plasmablade TnA handpiece via K083415). These devices are used with Pulsar I (K073057) and Pulsar II (K102029) Electrosurgical Generators. The devices provide radio-frequency energy for cutting (UPPP tip only) and coagulation of soft tissue and contain integrated suction for the evacuation of smoke and fluids from the surgical site. The PEAK Plasmablade ENT handpiece has integrated buttons for Cut and Coag, which may be used to operate the device, or it may be activated with an optional footswitch supplied with the Pulsar Generators.
Intended Use:	The PEAK PlasmaBlade UPPP is indicated for cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including, uvulopalatopharyngoplasty (UPPP) and tonsillectomy (Pharyngeal, Tubal, Palatine). The PEAK PlasmaBlade Suction Coagulator device is intended for use in surgical procedures such as general and otolaryngology (ENT) including, uvulopalatopharyngoplasty (UPPP), tonsillectomy, and adenoidectomy, where coagulation of tissue and suction of fluids are desired. It is not intended to be used as a dissection instrument.

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Technological Characteristics:

The PEAK PlasmaBlade UPPP and Suction Coagulator are similar to the predicate devices in that they are single use, sterile, electrosurgical instruments used to cut (UPPP only) and coagulate soft tissue utilizing RF powered distal ends. Both enable the suction of fluid and smoke from the surgical site.

Summary of Non-Clinical Testing:

The design and performance of the PEAK PlasmaBlade UPPP device were verified and validated through bench testing.

Electrical Safety of the PEAK PlasmaBlade UPPP was conducted in accordance with the following FDA recognized consensus standards:

Recognition Number	Standard	Title of Standard
19-4	IEC 60601-1:2005 3rd Edition And A1:2012	Medical electrical equipment-Part 1: General requirements for safety and Essential Performance
6-228	IEC 60601-2-2 Edition 5.0 2009-02	Medical electrical equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Comparative performance testing was conducted in an in-vivo animal model utilizing GLP. Performance and thermal effect of the PEAK PlasmaBlade UPPP and Suction Coagulator in the in-vivo model was equivalent to that of the predicate device.

Cadaveric testing was also conducted to further validate the devices for their intended use.

Summary of Clinical Tests: Clinical testing was not required for this product.

Conclusion: The indications for use, technology and performance characteristics of the PEAK PlasmaBlade UPPP and Suction Coagulator are equivalent to the predicate devices' and therefore Medtronic Advanced Energy claims Substantial equivalence to the predicate devices.